K121633

510(k) SUMMARY

SEP 18 2012

SUBMITTED BY: BECTON, DICKINSON AND COMPANY
10865 Road to the Cure, Suite 200
San Diego, CA 92121
Phone: 858-795-7890
Fax: 858-812-8505

CONTACT NAME: Gregory Payne

DATE PREPARED: September 12, 2012

DEVICE TRADE NAME: BD Veritor™ System for Rapid Detection of RSV

DEVICE COMMON NAME: Antigens Cf (including Cf Controls) Respiratory Syncytial Virus

DEVICE CLASSIFICATION: 21 CFR § 866.3480

PREDICATE DEVICES: Quidel QuickVue RSV 10 test

INTENDED USE:

The **BD Veritor™** System for Rapid Detection of Respiratory Syncytial Virus (RSV) is a chromatographic immunoassay with an instrumented read for the direct and qualitative detection of RSV fusion protein from nasopharyngeal washes/aspirates and nasopharyngeal swabs in transport media from patients suspected of having a viral respiratory infection. This test is intended for *in vitro* diagnostic use to aid in the diagnosis of RSV infections in infants and pediatric patients under the age of 20 years. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative test is presumptive. It is recommended that negative test results be confirmed by viral cell culture or an alternative method, such as a FDA-cleared molecular assay. The test is intended for professional and laboratory use. It is to be used in conjunction with the BD Veritor™ System Reader.

DEVICE DESCRIPTION:

The BD RSV test is a chromatographic assay to qualitatively detect RSV fusion protein in samples processed from respiratory specimens. The processed specimen is added to the test device where RSV viral antigens bind to anti-RSV antibodies conjugated to detector particles on the RSV test strip. The antigen-conjugate complex migrates across the test strip to the reaction area and is captured by an antibody line on the membrane. Results are interpreted by the BD Veritor™ System Reader, a portable electronic device which uses a reflectance-based measurement method to evaluate the line signal intensities on the assay test strip, and applies specific algorithms to determine the presence or absence of any target analyte(s). A liquid crystal display (LCD) on the instrument communicates the results to the operator.

DEVICE COMPARISON:

The BD Veritor™ System for Rapid Detection of RSV was compared to the Quidel QuickVue RSV 10 test (**k101918**)

Product Feature	BD Veritor™ System for RSV	Quidel QuickView RSV 10 test (k101918)
Intended Use	The BD Veritor™ System for Rapid Detection of Respiratory Syncytial Virus (RSV) is a chromatographic immunoassay with an instrumented read for the direct and qualitative detection of RSV fusion protein from nasopharyngeal washes/aspirates and nasopharyngeal swabs in transport media from patients suspected of having a viral respiratory infection. This test is intended for *in vitro* diagnostic use to aid in the diagnosis of RSV infections in infants and pediatric patients under the age of 20 years. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative test is presumptive. It is recommended that negative test results be confirmed by viral cell culture or an alternative method, such as a FDA-cleared molecular assay. The test is intended for professional and laboratory use. It is to be used in conjunction with the BD Veritor™ System Reader.	The QuickVue RSV 10 test is an immunoassay that allows for the rapid, qualitative detection of respiratory syncytial virus (RSV) antigen directly from nasopharyngeal swab 'and nasopharyngeal aspirate/wash specimens for symptomatic pediatric patients (less than six years old). The test is intended for use as an aid in the rapid diagnosis of acute RSV infection. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative test is presumptive. It is recommended that negative test results be confirmed by cell culture. The test is intended for professional and laboratory use.
Specimen Types	Nasopharyngeal swab in transport media, nasopharyngeal wash/aspirate	Nasopharyngeal swab, nasopharyngeal wash/aspirate
Assay Technology	Immunochromatographic	Immunochromatographic
Detection Format	An opto-electronic reader determines the line intensity at each of the spatially-defined test and control line positions, interprets the results using the scoring algorithm, and reports a positive, negative, or invalid result on the LCD screen based on pre-set thresholds.	Visual determination of presence or absence of pink-to-red Test Line and the appearance of a blue Procedural Control Line on the test strip indicate the presence of RSV antigen.
Qualitative	Yes	Yes
Total Assay Time	Approximately 10 minutes	10 minutes
Control format	• Kit RSV positive and RSV negative dry swab procedural control • Internal positive control • Internal negative control	• Kit RSV positive control swab • Kit RSV negative control swab • Internal control lines

SUMMARY OF PERFORMANCE DATA:

Analytical Sensitivity

The limit of detection (LOD) for the BD Veritor System for Rapid Detection of RSV test was established for the following RSV strains The LOD for each strain represents the lowest concentration producing a positivity rate of ≥95% based on testing 60 or more replicates.

Viral Strain	Calculated LOD ($TCID_{50}$/mL)	No. Positive / Total	% Positive
VR-26 (Long Subgroup A)	$1.43X10^5$	57/60	95.0
VR-955 (9320 subgroup B)	$3.98X10^4$	57/60	95.0
VR-1540 (A-2)	$1.94X10^3$	59/60	98.3
VR-1580 (Washington subgroup B)	$1.08X10^4$	58/60	96.7
VR-1400 (Wild Type subgroup B)	$2.96X10^3$	76/80	95.0

$TCID_{50}$/mL = 50% Tissue Culture Infectious Dose

Analytical Specificity (Cross Reactivity)

The BD Veritor System for Rapid Detection of RSV test was evaluated with bacteria and yeast at a target concentration of approximately 10^6 CFU/mL (CFU – Colony Forming Units) with the exception of *Fusobacterium nucleatum* which was tested at $1.5 X 10^5$.The viruses were evaluated at concentrations of 10^3 $TCID_{50}$/mL or greater. Of the microorganisms tested, none showed cross-reactivity in the RSV test.

Bacteriodes fragilis
Bordetella pertussis
Candida albicans
Chlamydia pneumoniae
Corynebacterium diphtherium
Escherichia coli
Fusobacterium nucleatum
Haemophilus influenzae
Haemophilus parainfluenzae
Kingella kingae
Klebsiella pneumoniae
Lactobacillus sp.
Legionella sp.
Moraxella catarrhalis
Mycobacterium tuberculosis
Mycoplasma pneumoniae
Neisseria gonorrhoeae
Neisseria meningitidis
Neisseria mucosa
Neisseria sp.*(Neisseria perflaus)*
Neisseria subflava
Peptostreptococcus anaerobius
Porphyromonas asaccharolyticus
Prevotella oralis
Propionibacterium acnes
Proteus mirabilis
Pseudomonas aeruginosa

Adenovirus, type 1
Adenovirus, type 7
Cytomegalovirus
Enterovirus
HSV Type 1
Human Coronavirus OC43
Human metapneumovirus (HMPV-27 A2)
Human Parainfluenza
Measles virus
Mumps virus
Rhinovirus

Serratia marcescens
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus mutans
Streptococcus pneumoniae
Streptococcus pyogenes
Streptococcus sp. Group C
Streptococcus sp. Group G
Streptococcus salivarius
Veillonella parvula

Interfering Substances

Various substances were evaluated with the BD Veritor System for Rapid Detection of RSV test. These substances included whole blood (2%) and various medications. No interference was noted with this assay for any of the substances at the concentrations tested.

Substance	Concentration Tested
Whole Blood	2%
4-Acetamidophenol	10 mg/mL
Acetylsalicylic acid	20 mg/mL
Chlorpheniramine maleate	5 mg/mL
Dextromethorphan	10 mg/mL
Diphenhydramine HCl	5 mg/mL
Guaiacol Glyceryl Ether	20 mg/mL
Ibuprofen	10 mg/mL
Loratidine	100 ng/mL
Menthol Throat Lozenges	10 mg/mL
Ayr Saline Nasal Gel	10 mg/mL
Oxymetazoline	0.05 mg/mL
Phenylephrine	1 mg/mL
Pseudoephedrine HCl	20 mg/mL
Three OTC mouthwashes	5 %
Four OTC nasal sprays	10 %
Four OTC throat drops	25 %
Homeopathic Allergy Medicine	10 mg/mL
Albuterol	0.083 mg/mL
Synagis	4 ug/mL
Amantadine Hydrochloride	500 ng/mL
Beclomethasone	500 ng/mL
Budesonide	500 ng/mL
Dexamethasone	10 mg/mL
Fexofenadine	500 ng/mL
FluMist	1%
Flunisolide	500 ng/mL
Fluticasone	500 ng/mL
Mometasone	500 ng/mL
Mupirocin	500 ng/mL
Oseltamivir	500 ng/mL
Purified Mucin Protein	1 mg/mL

Ribavirin	500 ng/mL
Rimantadine	500 ng/mL
Tobramycin	500 ng/mL
Triamcinolone	500 ng/mL
Zanamivir	1 mg/mL

Media Compatibility

Different types of transport media commonly used for the preservation and transport of respiratory specimens were evaluated for compatibility with the BD Veritor™ System for Rapid Detection of RSV test. The effects of frozen storage of transport media samples on the stability of the antigen were also evaluated in this study by storing them for 24 hours at -20 ± 5°C. The media tested were: Amies, Bartel ViraTrans, BD Universal, Earle's Minimal Essential, Hank's Balanced Salts, M4, M4-RT, M5, M6, Normal Saline, and Phosphate Buffered Saline. No interference or compatibility issues were seen.

CLINICAL STUDIES

Performance characteristics for the **BD Veritor** System for Rapid Detection of RSV test were established in multi-center clinical studies conducted at five U.S. trial sites during the 2011-2012 respiratory season. A total of 1174 prospectively collected specimens received in the laboratory with an order for respiratory virus testing were enrolled in the study, of which, 26 were noncompliant with the study protocol and one was noncompliant on the viral cell culture reference testing level. Removal of these specimens yields a total of 1147 specimens. One additional specimen had a final undetermined viral cell culture reference result which could not be verified. Removal of this specimen results in a total of 1146 specimens. A total of 1146 were evaluated using the **BD Veritor** System for Rapid Detection of RSV test and viral cell culture. The prospective specimens consisted of 440 Nasopharyngeal Wash /Aspirates (NPWA) and 706 nasopharyngeal swabs (NPS) in transport media from symptomatic patients. 44.3% of the samples were from females and 55.7% from males. 80% of patients were 2 years and under.

The performance of the **BD Veritor** System for Rapid Detection of RSV test was compared to an FDA cleared D^3 *Duet*™ DFA on R-Mix cell culture and is presented in the following tables

Summary of the performance of the BD Veritor System for Rapid Detection of RSV Test compared to viral cell culture by specimen type, all sites.

Clinical Performance- Veritor RSV to Viral Cell Culture, By Specimen Type				
		Culture		
Specimen Type	**Veritor RSV**	**P**	**N**	
NPS	**P**	153	9*	*162*
	N	20	524	*544*
		173	*533*	*706*
Reference Method: Culture Sensitivity: 88.4% (95% CI: 82.8%, 92.4%) Specificity: 98.3% (95% CI: 96.8%, 99.1%)				
NPWA	**P**	152	15**	*167*
	N	14	259	*273*
		166	*274*	*440*
Reference Method: Culture Sensitivity: 91.6% (95% CI: 86.3%, 94.9%) Specificity: 94.5% (95% CI: 91.2%, 96.7%)				

*of the 9 BD Veritor RSV Positive, Viral Cell Culture negative specimens, 6 were positive by FDA cleared Prodesse Pro Flu+ molecular assay
**of the 15 BD Veritor RSV Positive, Viral Cell Culture negative specimens, 8 were positive by FDA cleared Prodesse Pro Flu+ molecular assay

Reproducibility

The reproducibility of the BD Veritor System for Rapid Detection of RSV test was evaluated at three clinical laboratory sites. The reproducibility panel was composed of 12 simulated RSV samples. These included moderate positive samples, low positive samples (near the assay limit of detection), and high negative samples (i.e., containing very low concentrations of virus) and negative samples. The panel was tested by two operators at each site for five consecutive days. The results are summarized below.

BD Veritor™ RSV Reproducibility (% RSV positive results)				
Sample	**S1**	**S3**	**S5**	**Total**
High negative RSV	0% (0/30) (0%,11.3%)	3.3% (1/30) (0.6%,16.7%)	3.3% (1/30) (0.6%,16.7%)	2.2% (2/90) (0.6%,7.7%)
Low positive RSV	93.3% (28/30) (78.7%,98.2%)	76.7% (23/30) (59.1%,88.2%)	93.3% (28/30) (78.7%,98.2%)	87.8% (79/90) (79.4%,93%)
Moderate positive RSV	100% (30/30) (88.6%,100%)	100% (30/30) (88.6%,100%)	100% (30/30) (88.6%,100%)	100% (90/90) (95.9%,100%)
Negative	0% (0/30) (0%,11.3%)	0% (0/30) (0%,11.3%)	0% (0/30) (0%,11.3%)	0% (0/90) (0%,4.1%)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

SEP 18 2012

Becton, Dickinson and Company
c/o Gregory P. Payne, RAC
Director, Quality Systems and Regulatory Affairs
10865 Road to the Cure, Suite 200
San Diego, CA 92121

Re: k121633
Trade/Device Name: BD Veritor™ System for Rapid Detection of RSV
Regulation Number: 21 CFR §866.3480
Regulation Name: Respiratory syncytial virus serological reagents
Regulatory Class: Class I
Product Code: GQG
Dated: August 20, 2012
Received: August 22, 2012

Dear Mr. Payne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number: ___k 121633_____

Device Name: BD Veritor™ System for Rapid Detection of RSV

Indications for Use:

The **BD Veritor™** System for Rapid Detection of Respiratory Syncytial Virus (RSV) is a chromatographic immunoassay with an instrumented read for the direct and qualitative detection of RSV fusion protein from nasopharyngeal washes/aspirates and nasopharyngeal swabs in transport media from patients suspected of having a viral respiratory infection. This test is intended for *in vitro* diagnostic use to aid in the diagnosis of RSV infections in infants and pediatric patients under the age of 20 years. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative test is presumptive. It is recommended that negative test results be confirmed by viral cell culture or an alternative method, such as a FDA-cleared molecular assay. The test is intended for professional and laboratory use. It is to be used in conjunction with the BD Veritor™ System Reader.

Prescription Use __√__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices Evaluation and Safety (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K121633